REMARKS

Claims 1-22 remain in this application. In the Office Action dated March 31, 2005, Claims 1-3, 6-9, 11, 12 and 15-22 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,964,749 to Eckhouse *et al.* ("Eckhouse"), and Claims 4, 5, 10, 13 and 14 were rejected under 35 U.S.C. § 103 as being obvious over Eckhouse in combination with U.S. Patent No. 6,027,495 to Miller ("Miller '495"). For the following reasons, it is believed that these rejections are all overcome, and that the present claims should be allowed.

The applicant has amended the abstract of the invention in response to the Examiner's objection to the abstract. The abstract now contains less than 150 words, and it is believed that the Examiner's objection is overcome.

Independent Claims 1 and 11 have been amended to include the limitation that the "targeted structures [are] substantially adjacent to the non-targeted structures within the treatment area." Support for these amendments can be found in the Specification at, for example, page 16, lines 1-13). No new matter has been added.

The present invention is directed to methods and related systems of treating biologic tissue using pulse light, that includes treating tissue with a series of sub-pulses, where the periodicity of the pulses is less than the thermal relaxation time of targeted structures within the treatment area. Because the period of each sub-pulse is less than the thermal relaxation time of these targeted structures, the sub-pulses have a cumulative heating effect on the targeted structures (such as hair follicles and enlarged blood vessels, for instance), and can thus heat them to therapeutically useful temperatures. At the same time, because the inter-pulse delay time between sub-pulses is longer than the thermal relaxation time of non-targeted structures (such as small blood vessels, for instance), each sub-pulse in the series will act independently on these non-targeted structures. There is thus little or no cumulative heating effect on these non-targeted structures, and unwanted damage to these structures is minimized. This is true when both the targeted and non-targeted structures are substantially adjacent to one another within the treatment area (e.g., enlarged and regular-sized blood vessels located adjacent to one another at approximately the same depth within the patient's dermis). This technique can be

advantageously utilized to control the size of the targets to be heated and the maximum temperature to be reached. (See Specification at, for example, p. 16, lines 1-22).

This combination of the periodicity of the sub-pulses being less than the thermal relaxation time of targeted structures, and the inter-pulse delay being greater than the thermal relaxation time of substantially adjacent non-targeted structures, is not taught or suggested in the prior art of record. In the Office Action, the Examiner states that independent Claims 1 and 11, as well as dependent Claims 2, 3, 6-9, 12 and 15-22, are anticipated by the Eckhouse patent. However, Eckhouse relates to fundamentally different types of treatment methods compared to the present claims, and does not teach or suggest the novel combination of features presently recited.

Eckhouse describes various methods and apparatus for treating skin that include applying pulse light to the skin to heat and shrink collagen within the skin. (See Abstract). As described in Eckhouse, a short heating impulse, or "thermal shock," is applied to the collagen layers underlying the outer epidermis, which smooths or reduces wrinkles in the skin. A goal of the Eckhouse method is to heat the collagen without overheating of the epidermis. Thus, several techniques are described for avoiding overheating of the epidermis, including cooling the epidermis by applying a transparent cooling substance before or during treatment, or by controlling the delay time between application of a cooling substance and irradiation by radiation. (Col. 3, lines 21- 40). At one point, Eckhouse discusses an embodiment in which light energy is applied to the skin using a train of pulses with "variable delays between pulses in the range of 10's to 100's of milliseconds," stating that, in this pulse train embodiment, "the epidermis cools relative to the layer of collagen that is heated in the treatment." Eckhouse continues that the total number of pulses per train can be varied to account for variations in the patient's skin pigmentation, and "the pulse duration of each pulse in the train can be varied in order to enable cooling of the epidermis without cooling of the collagen." (See col. 5, lines 37-57).

This is very different from the treatment methods and systems recited in the present claims. For one, Eckhouse doesn't appear to describe a pulse train that comprises a "series of sub-pulses having a fractional duty cycle over a selected effective pulse duration, [and] a periodicity that is less than the thermal relaxation time of a targeted structure," as is recited in the

present claims. In the present invention, the period of the sub-pulses (i.e., the duration of the sub-pulse plus the interpulse delay time between the next pulse), is chosen to be less than the thermal relaxation time of the targeted structures in order to cause cumulative heating in these structures. Eckhouse doesn't discuss controlling the *period* of the pulses in the pulse train, only the *duration* of each individual pulse so as to enable cooling of the epidermis without cooling of the collagen during each "thermal shock" of the pulse train. In fact, Eckhouse's teaching that the interpulse delay between successive pulses in the pulse train is on the order of "10's to 100's of milliseconds" suggests that the *period* (pulse duration plus interpulse delay) of the pulses in the train is *greater* than the thermal relaxation time of the targeted structures, and therefore each "thermal shock" in the train acts independently on the targeted collagen. This is distinguishable from the present claims, where the goal is for each sub-pulse in the series of sub-pulses to cumulatively heat the targeted structure, while the surrounding non-targeted structures are spared.

Moreover, Eckhouse does not teach or suggest a method or system in which the target tissue contains targeted and non-targeted structures that are *substantially adjacent* to one another within the treatment area, and where the periodicity of the sub-pulses is less than the thermal relaxation time of the targeted structures, but the interpulse-delay between successive sub-pulses is greater than the thermal relaxation time of the non-targeted structures. Eckhouse instead describes a fundamentally different method for heating collagen, in which the pulse duration of each pulse in a pulse train is varied to enable cooling of the overlying epidermal layer without cooling the collagen. The epidermis is a separate layer from the underlying collagen layer. It is not *substantially adjacent* to the collagen, it is completely separate from and overlying the collagen layers. Eckhouse contains no teaching or suggestion whatsoever to control both the period <u>and</u> the interpulse delay of a series of sub-pulses so that the sub-pulses will provide cumulative heating to targeted structures (e.g. enlarged blood vessels) and little to no cumulative heating on non-targeted strucures (e.g. normal blood vessels), thus sparing these structures from destructive temperatures, where both the targeted and non-targeted structures are located substantially adjacent to one another (e.g. at substantially the same depth within the patient's dermis). Accordingly, it is believed that the Examiner's § 102 rejections are overcome.

The Examiner's statement that Eckhouse teaches inter-pulse delays time of between 0.5 to 10 milliseconds is erroneous, insofar as the Examiner attempts to combine this statement with

the description of the "thermal shock" collagen-treatment method elsewhere in the Eckhouse patent. It is correct that Eckhouse mentions a pulse train having delays of 0.5-10 milliseconds per pulse, but this is only in the context of a completely different cutaneous resurfacing method using an Er:YAG laser. In this technique, the outer epidermis is literally evaporated away to produce a "peeling" effect on the skin. This is entirely different from the present invention, in which targeted structures in the target area are heated, but adjacent non-targeted structures are spared by controlling the period and delay times of the sub-pulses. In Eckhouse's Er:YAG cutaneous resurfacing method, no distinction is made between targeted and non-targeted structures–the entirety of the tissue in the treatment area (i.e. the outer epidermis) is literally just evaporated away. (See col. 6, lines 16-32). Accordingly, the description of this ablative method is simply not relevant to the presently claimed methods and systems.

Furthermore, the secondary Miller '495 reference does not cure the deficiencies with respect to the Eckhouse patent. As discussed in the previous reply in this case, Miller '495 fails to teach or suggest the claimed combination of the periodicity of the sub-pulses being less than the thermal relaxation time of targeted structures, and the inter-pulse delay being greater than the thermal relaxation time of non-targeted structures. Because these features are not taught or suggested in the prior art of record, it is respectfully submitted that the Examiner's anticipation and obviousness rejections are overcome, and that the present claims should all be allowed.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Kevin T. Shaughnessy
Kevin T. Shaughnessy
Registration No. 51,014
Telephone: (978) 341-0036
Facsimile: (978) 341-0136

Concord, MA 01742-9133
Dated: 9/30/05